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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,201	01/27/2004	Yoji Tanijiri	019941-002010US	3314

20350 7590 11/16/2007

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,201	TANIJIRI ET AL.	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 08/29/2007 are acknowledged.

2. Claims 2-3 were cancelled.

3. Claims 1 and 6 were amended.

4. New claims 7-14 were added.

5. Claims 1 and 4-14 are included in the prosecution.

Response to Arguments

Rejection of claims 1-6 under 35 USC § 103(a)

6. Applicant's arguments, see page 5, filed 8/29/07, with respect to the rejection of claims 1-6 under 35 U.S.C. § 103(a) as being unpatentable over Ishibashi et al. (EP 1 125 576 A1) in view of Mizumoto et al. (EP 0 745 382 A1) have been fully considered and are persuasive. Therefore, the rejection of 3/26/07 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Shinoda et al. (WO 03/009831) and Ishibashi et al. (EP 1 125 576 A1).

7. It is noted that instant claim 4 is dependent on claim 3, which was cancelled. Appropriate correction is required.

NEW REJECTIONS:

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1 and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoda et al. (WO 03/009831) in view of Ishibashi et al. (EP 1 125 576 A1).

Please note that the document Shinoda et al. (EP 1 413 294 A1) (provided by applicant) is used as the English equivalent of the Japanese document WO 03/009831.

Claims are drawn to enteric sustained release fine particles of tamsulosin or its salt that can be contained in tablets that disintegrate in the buccal cavity and a method of producing the enteric sustained release fine particles.

Shinoda teaches "a composition comprising sustained-release fine particles for quick-disintegrating tablets in the buccal cavity" (Page 2, lines 5-6). The sustained release fine particles contain a drug, have been submitted to various types of sustained-release treatments such as those for enterosolubility, and have a mean particle diameter of approximately 0.1μm to approximately 350μm (Page 2, lines 14-20). The quick disintegrating tablets can be "easily taken, even without water, by persons with weak swallowing force, including the elderly, children, etc." (Page 2, lines 21-22). The drug in the sustained release particles is tamsulosin hydrochloride (Page 4, lines 1-2). Enterosoluble polymers used in the particles including hydroxypropylmethyl cellulose phthalate, carboxymethyl ethyl cellulose and methacrylic acid-methyl methacrylate copolymer are disclosed (Page 8, lines 6-9). Higher fatty acids and wax-like substances are disclosed (Page 8, lines 10-12). Ethyl acrylate-methyl methacrylate copolymer is disclosed (Page 8, line 19). Ethyl cellulose is disclosed as another polymer used for the sustained release fine particles (Page 4, line 9). Dissolution tests for tablets with the

sustained release fine particles, based on the Japanese Pharmacopoeia, are disclosed (Page 13, lines 5-10).

Shinoda does not expressly teach the dissolution of tamsulosin or its salt is controlled by a controlling film and/or matrix.

Ishibashi teaches a process for producing spherical fine particles containing a drug that is an easily swallowed, controlled release preparation (Abstract). The fine particles are coated with "enteric coating and slow-release coating" (page 6, lines 3-7). Regarding the coating of the fine particles, Ishibashi teaches coating with "a water-insoluble and water impermeable acrylic resin polymer, ... coating with a multilayer film, ... coating with a mixture of enteric coating agent and water-insoluble coating agent, ... (page 6, lines 17-28). Ishibashi also teaches "examples of easily swallowed, controlled release preparations" (page 6, lines 31-46) and that the "coated drug-containing spherical microparticles can also be used in the production of conventionally used preparations such as ... tablets" (page 6, lines 47-48). The mean particle size is 200μm, and the preferable particle size is 60-150μm (page 5, lines 49-50). Dissolution tests (according to the Japanese Pharmacopeia) were performed on the coated fine particles at pH 6.8 to test the enteric coating release (page 8, lines 32-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising sustained-release fine particles of tamsulosin for quick-disintegrating tablets in the buccal cavity, as suggested by Shinoda, combine it with the controlled release preparation with spherical fine particles containing a drug, as taught by Ishibashi, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Shinoda teaches that quick disintegrating tablets can be "easily taken, even without water, by persons with weak swallowing force, including the elderly, children, etc."

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of enteric sustained release fine particles for tablets that disintegrate in the buccal cavity would have been obvious to one skilled in the art over the sustained-release fine particles of tamsulosin for quick-disintegrating tablets in the buccal cavity taught by Shinoda. The limitation of the enterosoluble polymers, the higher fatty acid, and the wax would have been obvious over the enterosoluble polymers, higher fatty acid and wax taught by Shinoda. The limitation of the particle size would have been obvious over the particle size range taught by Shinoda.

Regarding the dissolution test limitations disclosed in instant claims 1 and 6, Shinoda discloses the dissolution tests of the tablets based on the Japanese Pharmacopoeia and Ishibashi teaches testing the dissolution of the preparation. Since the fine particles have been enterically coated, a person with ordinary skill in the art would find it obvious to test a tablet containing the enterically coated particles first at a low pH (1.2) to ensure a low dissolution rate in the gastric milieu and then at a higher

pH (6.8) to ensure the release of the drug in the intestinal milieu. A person with ordinary skill in the art would use the protocols of testing outlined in the pharmacopoeia (in the instant case the Japanese Pharmacopoeia was used). Accordingly, a person with ordinary skill in the art would modify the formulation of the tablet and the enterically coated fine particles in order to achieve the desired dissolution profile for the particular drug (in this case tamsulosin hydrochloride) during routine optimization.

Regarding instant claims 4 and 10-12, the limitation of the dissolution and sustained release of tamsulosin controlled by a controlling film or matrix would have been obvious to one skilled in the art over the multilayer films for controlled release, as taught by Ishibashi.

Regarding instant claim 5, the limitation of a layer of enterosoluble base as the outermost layer would have been obvious because the enteric coating has to protect the fine particles from gastric acid degradation and allow the dissolution in the intestines and one skilled in the art would use the enteric layer as the outermost layer and the water insoluble layer as the inner layer.

Regarding instant claim 6, the limitation of a method of producing enteric sustained-release fine particles for tablets that disintegrate in the buccal cavity would have been obvious over the processes taught by Shinoda and Ishibashi.

Regarding instant claims 7-9, the limitations of the water insoluble polymer and the enterosoluble polymer would have been obvious over the water insoluble polymers and enterosoluble polymers taught by Shinoda and Ishibashi.

Regarding instant claim 13, the particle size limitation would have been obvious over the particle size range taught by Shinoda.

Regarding instant claim 14, the limitation of the enteric sustained-release fine particles made into tablets would have been obvious over the tablets taught by Shinoda and Ishibashi.

Conclusion

10. Due to the new grounds of rejection, this action is made non-final.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600